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United States Senate
WASHINGTON, DC 20510

August 3, 2000

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Madam Secretary:

In recent weeks, we have heard from many concerned constituents, including oncologists, hospitals, and chemotherapy patients and their families, about the administrative initiative by the Department of Health and Human Services (HHS) to change the Medicare reimbursement structure for many cancer drugs. Because we are concerned that this new initiative could affect both the quality and quantity of care that Medicare cancer patients receive, we urge you to carefully reconsider your proposed change.

As you know, in the Balanced Budget Act of 1997 (BBA), Congress instructed HHS to base Medicare reimbursement for cancer drugs on 95 percent of the "average wholesale price," or AWP, a term widely understood and indeed defined by HHS manuals to reference amounts reflected in specified publications. Later, Congress pegged reimbursement for drugs in the outpatient setting to the same definition of AWP.

Now, HHS has announced a plan to furnish Medicare carriers with drug prices from catalogues and group purchasing organization price lists to use instead of AWP for drugs reimbursed by Medicare. These data will result in a lower AWP than that currently reimbursed by the program.

We understand HHS' concerns that the reimbursement rate for many drugs may exceed the actual acquisition costs. According to our oncologists, however, this margin pays for wastage, spillage, and administrative costs — including the extra costs of skilled personnel, inventory, and preparation — for which they say they are inadequately reimbursed. They tell us that, although Medicare makes a payment for chemotherapy administration services, the payment is only a fraction of what is necessary to cover their expenses, and they use payment amounts for drugs to help cover these expenses.

From our hospitals, we have heard that if the HHS initiative is implemented, the result will be reimbursement rates lower than the acquisition costs of many hospitals. A recent study of the Association of Community Cancer Centers (ACCC) found that if drugs are reimbursed at the current rate — 95 percent of AWP — cancer centers would break even. ACCC estimates that if HHS' new definition of AWP is instead used for reimbursement rates, it will be difficult for

Defendants' Exhibit

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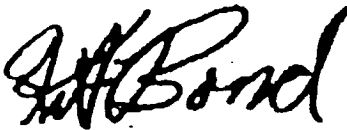
hospitals to continue to be a source of chemotherapy and supportive care for cancer patients. Such an estimate is disturbing, especially in light of the fact that just last fall, Congress saw the need to amend the BBA to provide additional payments to hospitals for cancer therapy drugs.

It is disturbing that HHS would now seek to circumvent Congressional actions by redefining AWP. We see no basis for such action in any of our previous legislation, and certainly HHS' unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate. Medicare beneficiaries with cancer should feel confident that they will receive the care they need, in the setting they choose, without risk of arbitrary and unexpected reductions in reimbursement that may compel their doctors to refer them to a different facility for treatment.

We know you share our ultimate goal of providing the best cancer care to our seniors, and we hope that you will adequately address our concerns. We urge you to reconsider your proposed initiative to ensure that Medicare beneficiaries with cancer are assured access to the quality, comprehensive care they need and deserve.

We appreciate your commitment to Medicare beneficiaries and look forward to hearing from you soon about this matter.

Sincerely,

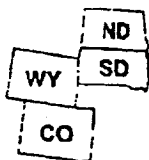


Christopher S. Bond



John Ashcroft

cc: Ms. Nancy-Ann Min DeParle
Administrator, HCFA




Medicare

600 Grant Street, Suite 600
Denver, CO 80203-3527

MEMORANDUM

To: All the Physicians Who Wrote In About Lupron

From: Grant E. Steffen, MD 

RE: Average Wholesale Price (AWP) and Acquisition Cost (AC)

Date: August 6, 1996

The Regional Office of HCFA has instructed me to write this letter retracting my request for invoices made in my memo to you dated July 11, 1996. This letter will also serve to notify you that there will be no, nor was there any reduction in the payment for either Zoladex or Lupron. This carrier will continue to allow payment on the basis of the AWP.

Thank you for your patience.